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AdvaMed
Advanced Medical Technology Association

March 11, 2005

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20857

RE: Docket No 2003N-0535, Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: Food and Drug Administration Medical Products Reporting Program

Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, I am pleased to submit comments on whether FDA's MedWatch forms (Forms 3500 and 3500A) should be amended to improve the utilization of available space and to allow for information on non-device products to share data fields with items D-10 and D-11.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world.

AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

General Comments

For the device industry this is the second modification of the MedWatch form in about 2 years. We would like to express to the Agency our dissatisfaction with its approach of modifying the form on separate occasions. It is costly and time consuming to update the systems used to generate computerized forms and would like the Agency to take this into consideration as it contemplates updates to the form. In this situation, we would have

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preferred FDA to have made all the modifications (those from 2 years ago and the new modifications) at one time.

Specific Comments
In response to the specific questions listed in the *Federal Register*, AdvaMed provides the following responses:

1. The accuracy of FDA's estimate of the burden of proposed collection of information, including the validity of the methodology and assumptions used.

The Estimated Annual Reporting Burden (Table 1) does not include the hours necessary for firms to retrain staff in the over 28 changes to the MedWatch form including: new choices (for adverse event/product problems, new outcomes, new questions on pregnancy/breast feeding, addition of PMA/510K numbers and new 30 day report type), deletion of choices (device available for evaluation, device returned), and the rearrangement and relettering of data blocks. Firms using computer generated MedWatch form must also modify and validate their existing computer system to reflect the modified form. This type of wholesale change may potentially undermine the effectiveness of current adverse event reporting systems.

2. Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, ... and other forms of information technology.

Firms using computerized forms must plan and budget for software modifications and subsequent validation of the new form. Firms cannot start such activities until an approved, final form is available. AdvaMed requests a 6-month grace period between FDA's promulgation of the final form and the requirement for its implementation by industry to modify and validate computerized systems generating the form and to retrain users of the form.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

Block B.1. Neither § 803.3 [Federal Register vol. 70(38), p. 9519 (February 28, 2005)] nor § 803.52 (p. 9527) defines "Product Switch," so it is unclear whether this term is relevant to medical device manufacturers. The term should be defined and its applicability to device manufacturers clarified if the applicability is not clear from the definition. The term "Adverse Event" should be "Serious Adverse Event" for consistency with § 803.3. (For further discussion of adverse events, please see the section about Block B.2., below.)

Block B.2. The availability of boxes to classify an adverse event as "Not Serious" or "No Harm" is problematic. An adverse event that is not serious is not reportable under § 803.3. An adverse event that causes "No Harm" is, a fortiori, not reportable and, in fact, an oxymoron. The box, "Important Medical Events," is also of concern because, like the two previous terms, "Important Medical Events" is not discussed in § 803.52. Impliedly, these three categories are not relevant to

medical device manufacturers. The regulations should make explicit their lack of applicability. [Section II.A. of the above-referenced Federal Register states, "We do not intend these changes to have any effect on the substantive requirements of part 803."] If "Important Medical Events" is applicable, the regulation should define it. However, the term appears redundant, since the form already captures "death, life-threatening, hospitalization – initial or prolonged, disability or permanent damage, congenital anomaly/birth defect, and required intervention to prevent permanent impairment/damage."

Block H, as discussed in § 803.52, is Block J in the new form. Therefore, FDA should revise § 803.52 to reflect this change.

Block I.6. The regulations do not provide any information regarding the addition of "IDE." § 812.150(b)(1) requires the sponsor to report unanticipated adverse device effects as defined in § 812.3(s). Form 3500A is not suitable for such reports, and adverse events that are not unanticipated have not been reportable on Form 3500A.

Block J.1. This information is redundant with the information in blocks B.1 and B.2.

Block J.3. The box, "not returned to mfr." should be retained unless there is a code for devices not returned to the manufacturer. If the box is not retained and there is no code, manufacturers will be required to attach another page merely to state that the device was not returned.
Block J.5. The significance, if any, of changing the title of this block from "Labeled for single use?" to "Indicated for Single Use" is unclear.

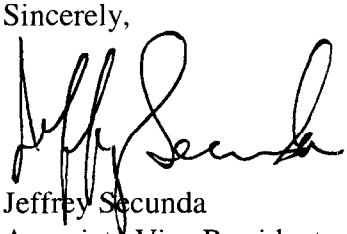
AdvaMed has noticed that the planned revision of the MDR regulation (Docket No. 2004N-0527) does not consider any of the proposed changes to the Medwatch 3500A form. This makes the numerous references in the MDR regulation to the 3500A form incorrect. Furthermore, there are no instructions, guidance or explanation concerning new terms such as; Important Medical Events, Not Serious and No Harm. AdvaMed believes that without adequate guidance there will not be any value in the proposed changes to the 3500A form, and may potentially undermine the effectiveness of the current adverse event reporting system.

Conclusion
AdvaMed feels that the proposed changes to the MedWatch forms have not been completely evaluated as to their burden on respondents. Furthermore, rather than piece meal changes in the form, AdvaMed would support a more comprehensive look at the 3500A form and the 21CFR803 regulation. The absence of adequate definitions and guidance for new terms, and the lack of coordination with proposed changes to 21CFR803, renders the proposed changes to form 3500A as without utility.

Finally, AdvaMed strongly requests that FDA provide a six (6) month implementation period for any changes to the MedWatch forms, to provide adequate time for validation of computerized forms.

If you have any questions, feel free to contact me at 202-434-7224 or jsecunda@advamed.org.

Sincerely,



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